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A Comparative Study of Regulatory Requirements and Marketing Authorization of Herbal Medicines in INDIA, THE US, and EUROPE

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ABSTRACT:
India's formal oversight of herbal medicines is rooted in the Drugs & Cosmetics Act, 1940 (D&C Act) and rules, with dedicated provisions for Ayurveda, Siddha, and Unani (ASU) medicines. Schedule T (2000) codified GMP for ASU drugs, while Rule 158-B clarified evidence/experience requirements for ASU proprietary medicines. In 2015, the Government of India introduced phytopharmaceuticals via GSR 918(E), creating a modern "new drug" category (quality, nonclinical, clinical data assessed by CDSCO) distinct from classical ASU formulations. **United States**: In 1994, the Dietary Supplement Health and Education Act (DSHEA) established a distinct regulatory category for dietary supplements, under which most herbal products are marketed. Under DSHEA, FDA does not pre-approve supplements for safety/effectiveness; firms must follow labeling rules and are responsible for ensuring safety and quality. Manufacturing quality is governed by 21 CFR Part 111 (cGMP for dietary supplements), while structure/function claims require the 101.93 disclaimer and may not be disease claims. **European Union**: The EU established a harmonized framework under Directive 2001/83/EC (Community Code), later amended by Directive 2004/24/EC (the "Herbal Directive") to create a simplified Traditional Herbal Medicinal Products (THMP) registration. THMP requires ≥30 years of medicinal use (including ≥15 years within the EU), evidence of safety and plausible efficacy, and is limited to non-injectable products intended for self-care; many dossiers rely on HMPC monographs and list entries. The study concludes that while regulatory divergence persists, convergence is both possible and desirable. The path forward lies in: Recognizing traditional knowledge alongside modern scientific evidence. Harmonizing GMP/GACP standards to secure global supply chains. Integrating PV systems into a shared platform. Leveraging digital innovations to streamline submissions and safety monitoring. In essence, a hybrid regulatory model combining cultural respect for traditional systems with modern scientific rigor represents the future of herbal medicine regulation worldwide.
Keywords: INDIA, THE US, EUROPE, Ayurveda, Siddha, GMP, Herbal Medicinal Products, USFDA

Introduction

The global demand for herbal medicines has grown significantly over the past few decades, driven by increasing consumer preference for natural therapies, the perception of fewer side effects compared to synthetic drugs, and the integration of traditional medicine into modern healthcare systems. Herbal formulations are widely used not only in developing countries, where traditional medicine is deeply rooted in cultural practices, but also in developed markets such as the United States and Europe, where complementary and alternative medicine (CAM) has gained regulatory and commercial prominence. Despite this growing demand, the regulatory requirements and marketing authorization pathways for herbal medicines remain highly heterogeneous across jurisdictions. In India, the Ministry of AYUSH (Ayurveda, Yoga, Unani, Siddha, and Homeopathy) oversees the regulation of herbal medicines, with an emphasis on traditional knowledge and pharmacopeial standards. However, challenges remain in standardization, quality control, clinical validation, and global acceptance of Indian herbal formulations. In contrast, the European Union (EU) has established a well-structured framework under the Traditional Herbal Medicinal Products Directive (THMPD, 2004/24/EC), which provides a simplified registration process for herbal medicines with a history of traditional use. This framework emphasizes safety, quality, and plausibility of efficacy, offering a balance between evidence requirements and market accessibility. Meanwhile, the United States Food and Drug Administration (USFDA) classifies most herbal products as dietary supplements under the Dietary Supplement Health and Education Act (DSHEA, 1994), which imposes less stringent pre-market evaluation but requires post-market surveillance and compliance with labeling standards. These differing regulatory philosophies traditional-use based in the EU, dietary supplement categorization in the US, and AYUSH-driven traditional frameworks in India create both opportunities and barriers for global harmonization and trade.

The rationale for this study arises from the following considerations:

1. Public Health Relevance: Herbal medicines are extensively consumed worldwide, often without adequate regulatory oversight. Comparative evaluation of regulatory frameworks can ensure patient safety, efficacy, and product quality.
2. Regulatory Disparities: Major markets adopt diverse approaches—ranging from simplified traditional-use registrations (EU) to dietary supplement classification (US) to AYUSH-driven oversight (India). These

variations impact product development, approval timelines, and international marketing potential.

3. Market Expansion and Trade: India, with its rich heritage of Ayurveda and traditional medicine, has immense potential to expand exports of herbal medicines. However, divergent regulatory requirements in the US and EU often hinder global market access. A comparative study can identify gaps and strategies to improve international acceptance of Indian herbal products.
4. Scientific and Policy Gaps: Issues such as standardization, pharmacovigilance, clinical validation, and harmonization of quality benchmarks remain inadequately addressed in existing literature. A comprehensive comparative analysis will bridge these gaps, informing both policymakers and industry stakeholders.
5. Contribution to Global Harmonization: By systematically comparing India, the US, and Europe, the study will generate insights into best practices and highlight opportunities for aligning regulatory frameworks, ultimately supporting the World Health Organization's (WHO) call for strengthening the safety, efficacy, and quality assurance of traditional and complementary medicines.

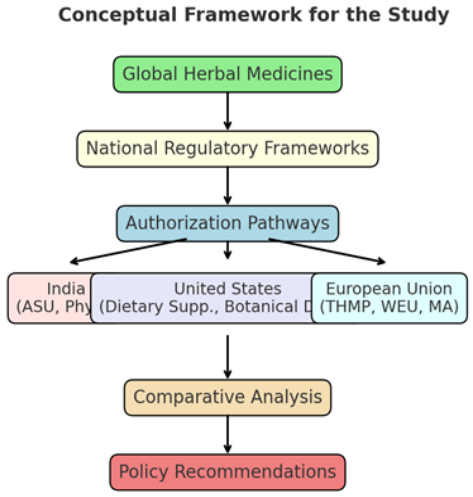

Figure.1: Conceptual Framework for the Study

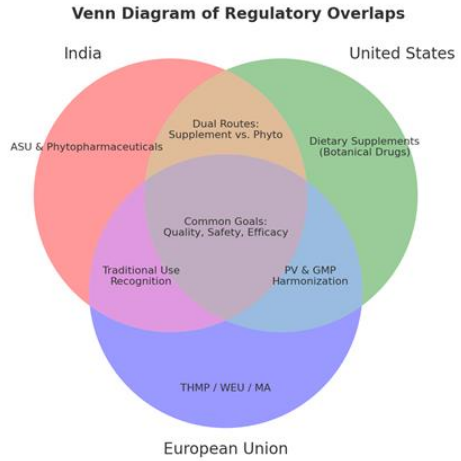

Figure.2: Venn diagram of Regulatory Overlaps

Methodology

Comparative Legal and Regulatory Research Methodology

The present study adopts a comparative legal-regulatory research methodology, which emphasizes the systematic collection, analysis, and comparison of statutory texts, regulatory guidelines, and authoritative reports from India, the United States, and the European Union. This approach was selected because herbal medicines are primarily governed by policy instruments and regulations, not experimental laboratory procedures. Thus, qualitative analysis of documents forms the central methodological strategy.

Features

1. Doctrinal legal analysis – Review of statutory laws, government notifications, and international guidelines.
2. Comparative analysis – Cross-examination of how different jurisdictions classify, regulate, and monitor herbal medicines.
3. Thematic coding – Regulatory requirements were broken down into five core dimensions: classification, approval pathways, evidence, quality standards, and pharmacovigilance.
4. Matrix development – Structured tables constructed to highlight similarities, divergences, and gaps.
5. Visualization – Flowcharts and models developed to demonstrate authorization decision flows and comparative overlaps.

Table .1: Methodological Approach

Method	Description	Application
Doctrinal legal review	Analysis of laws, directives, rules	D&C Act, DSHEA, EU Directives
Comparative policy analysis	Cross-country comparison	India vs. US vs. EU
Thematic categorization	Coding into core dimensions	Classification, claims, quality
Matrix construction	Tables for structured insights	Evidence, GMP, claims
Visualization	Flowcharts, diagrams	Pathways & overlaps

Framework for Analysis

The comparative analysis framework was structured around five thematic dimensions:

Regulatory Classification

India: ASU, phytopharmaceuticals, nutraceuticals
US: dietary supplements, botanical drugs
EU: THMP, WEU, Full MA

Authorization Pathways

- Traditional-use vs. drug-like routes
- State vs. central approvals (India), NDI notification vs. NDA (US), THMP vs. MA (EU)

Evidence Standards

- Traditional use evidence
- Bibliographic references
- Nonclinical/clinical data requirements

Quality Standards

- GMP (Schedule T, 21 CFR Part 111, EU-GMP)
- GACP requirements (WHO, EMA)
- Pharmacopoeial standards

Claims & Pharmacovigilance

- Labeling, permissible claims, disclaimers

- **PV systems:** AYUSH-PvPI, FDA Med Watch, EMA Eudra Vigilance

Limitations

Despite methodological rigor, this study acknowledges several limitations:

1. **Dynamic nature of regulation** – Regulatory updates (e.g., EMA GACP Rev. 2025, FDA botanical NDA guidance revisions) may occur after data collection.
2. **Scope restriction** – Only India, US, and EU are covered; other major herbal systems (e.g., China's TCM, Japan's Kampo) are excluded.
3. **Data access** – Some regulatory documents (e.g., FDA complete NDA dossiers, CDSCO proprietary filings) are not publicly available.
4. **Comparability issues**
   Direct comparison is challenging where regulatory philosophies differ (e.g., supplement vs. medicine categorization).
5. **Non-quantitative**
   The study is qualitative, not experimental; hence, conclusions focus on policy insights rather than clinical outcomes.

Results and Discussion

Table .2: High-Level Regulatory Requirements for Herbal Medicines

Dimension	India	United States	European Union
Legal classification	ASU medicines (classical/proprietary), Phytopharmaceuticals, Nutraceuticals (FSSAI)	Dietary supplements (DSHEA), Botanical drugs (NDA)	THMP (traditional), WEU (literature-based), Full MA
Primary legislation	Drugs & Cosmetics Act (1940), Rules, Notifications	DSHEA (1994), 21 CFR Parts 111 & 101.93	Directive 2001/83/EC, Directive 2004/24/EC
Regulatory authority	CDSCO & Ministry of AYUSH	FDA (CDER, CFSAN)	EMA + National Competent Authorities (NCAs)
Evidence type	Traditional text support, experiential evidence, clinical data for phytopharm.	Supplements: no pre-approval; NDIN if applicable; Botanical NDA: full nonclinical/clinical	THMP: traditional use (30/15 yrs); WEU: 10 yrs EU + literature; MA: full trials
GMP requirements	Schedule T (ASU GMP), CDSCO GMP (phytopharm.)	21 CFR Part 111 (supplements); drug GMP (botanical NDA)	EU-GMP; GACP for cultivation
Claims allowed	ASU drug claims; phytopharm. therapeutic claims; nutraceutical limited claims	Structure/function claims + disclaimer; no disease claims unless NDA	THMP: traditional indications; WEU/MA: conventional therapeutic claims
PV systems	AYUSH PvPI, CDSCO	SAER reporting (MedWatch)	EudraVigilance

Marketing Authorization Pathways

India:

- ASU Medicines → licensed at State level, based on classical texts or Rule 158-B.
- Phytopharmaceuticals → new drug route under CDSCO, requires dossier with quality/nonclinical/clinical data.
- Nutraceuticals → FSSAI regulations, food-like claims only.

US:

- Dietary supplements → market entry without pre-approval, compliance with DSHEA, cGMP, labeling rules.
- Botanical drugs → IND → NDA, same requirements as chemical drugs.

EU:

- THMP → simplified traditional-use registration.
- WEU → well-established use, bibliographic literature.
- Full MA → standard clinical trial-based dossier.

Table 3: Evidence Requirements by Pathway

Jurisdiction	Traditional-use route	Modern/drug-like route
India	Classical ASU texts; Rule 158-B requires safety/effectiveness based on traditional use & references	Phytopharmaceuticals: full nonclinical + clinical package
US	Supplements: history of safe use; NDIN for new dietary ingredients; no efficacy data required	Botanical drugs: IND & NDA → Phase I–III clinical trials
EU	THMP: ≥30 yrs (≥15 EU) traditional use + safety + plausible efficacy	WEU: ≥10 yrs EU use + published data; Full MA: full preclinical + clinical

Table 4: Manufacturing Quality Standards

Aspect	India	US	EU
Cultivation/collection	WHO GACP referenced; NMPB standards	No binding federal GACP; voluntary standards by AHPA	EMA/HMPC GACP (Rev.1, 2025)
GMP	Schedule T (ASU GMP); CDSCO GMP for phytopharm.	21 CFR Part 111 (supplements); drug GMP for botanicals	EU-GMP; Ph. Eur. quality monographs
Pharmacopoeias	Ayurvedic Pharmacopoeia of India; Indian Pharmacopoeia	USP–NF monographs for botanicals	European Pharmacopoeia

Table 5: Labeling and Claims

Jurisdiction	Allowed claims	Restrictions
India	Therapeutic claims (ASU); drug claims for phytopharm.	Nutraceuticals limited to health/wellness, no curative claims
US	Structure/function claims with disclaimer; health maintenance	Disease claims prohibited unless NDA approval
EU	THMP: traditional use claims only (minor conditions)	Full MA/WEU claims require efficacy data; self-care only for THMP

Table 6: Pharmacovigilance Framework

Jurisdiction	PV obligations	System
India	Mandatory ADR reporting under AYUSH PvPI; CDSCO oversight for phytopharm.	Multi-tiered PV network (peripheral → national centers)
US	Mandatory Serious Adverse Event Reports (SAERs) for supplements (21 USC 379aa-1)	FDA MedWatch, Safety Reporting Portal
EU	MA holders must report ADRs via EudraVigilance; THMP products may have reduced PSUR obligations	EMA centralized safety database

Table 7: Analytical Framework

Dimension	India	US	EU
Classification	ASU, Phytopharm., Nutraceuticals	Dietary supplements, Botanical drugs	THMP, WEU, Full MA
Pathways	Rule 158-B, GSR 918(E)	DSHEA/Part 111, Botanical NDA	Directive 2004/24/EC, 2001/83/EC
Evidence	Traditional use + limited trials	NDI notification, clinical NDA	30/15 yrs traditional use, 10 yrs WEU
Quality	Schedule T GMP	21 CFR Part 111	EU-GMP, GACP
PV	ASU&H PV Program	SAER reporting	EudraVigilance

Table 8: Limitations of the Study

Limitation	Impact	Mitigation Strategy
Frequent updates	Risk of outdated content	Use of most recent official documents
Restricted scope	Exclusion of TCM, Kampo	Clear boundary definition
Limited access to proprietary data	Missing case-level insights	Reliance on official summaries
Philosophical divergence	Reduced comparability	Use of thematic framework
Qualitative approach	No statistical validation	Triangulation via multiple sources

Discussion

Interpretation of Findings

The comparative analysis reveals three distinct regulatory philosophies:

India operates a dual system:

- Traditional ASU medicines licensed primarily based on classical texts and experiential evidence.
- Phytopharmaceuticals, requiring modern drug-like dossiers with quality, nonclinical, and clinical evidence.

United States applies a bifurcated approach:

- Dietary supplements, permitted under DSHEA with minimal pre-market burden, but restricted to structure/function claims.
- Botanical drugs, requiring full IND → NDA process, on par with conventional pharmaceuticals.

European Union provides a tiered authorization system:

- THMP (simplified traditional registration),
- WEU (literature-based), and
- Full MA (full clinical dossier).

Insight: Despite divergences in categorization and evidentiary thresholds, all three systems share a common regulatory core-ensuring quality, safety, and efficacy through GMP, GACP, and pharmacovigilance systems.

Strategic Implications for Manufacturers/Exporters: For herbal medicine companies seeking global commercialization, regulatory divergence has significant implications:

India to EU/US exports:

- Products licensed as ASU may not meet EU's THMP requirements unless 30/15-year use can be documented.
- US importers may reclassify ASU medicines as dietary supplements, restricting claims.

US to EU exports:

- Supplements marketed freely in the US often require THMP registration or WEU authorization in Europe.
- Manufacturers must prepare bibliographic evidence dossiers and adapt labeling to EU standards.

EU to India/US exports:

- THMP-registered products may be marketed as supplements in the US but may need new approvals in India if not aligned with ASU categories.

Challenges in Harmonization

Divergent product classification

- Same herbal product may be a "medicine" (EU), "supplement" (US), or "ASU" (India).
- Inconsistent evidence requirements
- EU accepts bibliographic evidence (THMP/WEU).
- India recognizes traditional texts.
- US requires full clinical trials for NDAs.

Claims and labeling conflicts

- US prohibits disease claims for supplements.
- EU permits only traditional-use or self-care indications.
- India allows therapeutic claims for ASU but restricts nutraceuticals.

Pharmacovigilance interoperability gaps

- India: PvPI (ASU&H).
- US: SAER for supplements.
- EU: EudraVigilance.
- No global signal-sharing mechanism exists.

Conclusion

The comparative study of regulatory frameworks for herbal medicines in India, the United States, and the European Union

underscores both the diversity of approaches and the shared commitment to public health protection.

Regulatory Classification

- India recognizes ASU medicines (traditional formulations) and phytopharmaceuticals (modern drug category), with nutraceuticals under FSSAI.
- The US divides herbal products into dietary supplements (regulated as foods) and botanical drugs (regulated as pharmaceuticals).
- The EU employs a tiered medicinal framework with THMP, WEU, and Full MA.

Evidence Requirements

- India and EU accept traditional use evidence (texts, bibliographic data), while the US requires clinical trials for any drug approval.
- Supplements in the US require only history of safe use, not efficacy trials.

Manufacturing Standards

- India applies Schedule T GMP for ASU, CDSCO GMP for phytopharm.
- The US mandates 21 CFR Part 111 for supplements and drug GMP for NDAs.
- The EU enforces EU-GMP and GACP, harmonized across member states.

Claims and Labeling

- India allows therapeutic claims for ASU/phytopharm., but restricts nutraceuticals.
- US supplements may make structure/function claims with disclaimers, but no disease claims.
- EU THMP claims are limited to traditional indications for minor conditions.

Pharmacovigilance

- India: AYUSH-PvPI with a multi-tier reporting network.
- US: Serious Adverse Event Reports (SAERs) required for supplements, via MedWatch.
- EU: Centralized ADR reporting through Eudra Vigilance.

Recommendations for Regulators

Harmonization of Definitions

- Develop WHO-led guidelines for uniform classification of herbal medicines.
- Reduce confusion across medicine vs. supplement vs. nutraceutical categories.

Mutual Recognition of Evidence

- EU's bibliographic evidence model and India's traditional text recognition could be cross-referenced.
- Promote global acceptance of traditional knowledge databases (e.g., TKDL India).

Unified Quality Standards

- Global adoption of GACP + GMP harmonization to ensure supply chain integrity.
- Promote cross-recognition of pharmacopoeial monographs.

Pharmacovigilance Integration

- Establish a global herbal ADR database, integrating India's PvPI, FDA MedWatch, and EMA EudraVigilance.
- Encourage patient-driven ADR reporting through mobile apps and digital platforms.

Digital Transformation

- Align eCTD submissions across US, EU, and India.
- Leverage AI/ML tools for literature mining, dossier review, and ADR signal detection.

Recommendations for Industry

1. **Regulatory Intelligence**
   - Maintain dedicated teams to track evolving laws (e.g., EU GACP Rev.1, FDA botanical guidance).
2. **Adaptive Product Strategy**
   - Position the same product differently across markets (e.g., supplement in US, THMP in EU).
3. **Evidence Development**
   - Invest in bibliographic dossiers and clinical bridging studies to access high-regulation markets.
4. **Quality Assurance**
   - Implement globally harmonized GMP/GACP compliance to ease export certification.
5. **Collaboration**
   - Engage with regulators, WHO, and trade associations to influence policy development.

Research Contributions

This thesis contributes by:

- Mapping the tri-regional regulatory frameworks (India, US, EU) in a systematic comparative model.
- Constructing comprehensive comparative matrices covering classification, authorization, evidence, quality, claims, and PV.
- Identifying knowledge gaps and barriers to harmonization, especially regarding evidence acceptance and claim restrictions.
- Proposing practical pathways for convergence under WHO/ICH-like models.
- Highlighting the role of digital tools and AI in future herbal regulation.

Future Directions

Expanding the Comparative Scope

- Inclusion of China (TCM), Japan (Kampo), and African traditional medicine frameworks.

Integration of Real-World Evidence (RWE)

- Leveraging electronic health records and post-marketing surveillance for herbal safety/efficacy validation.

Advanced Analytical Tools

- Adoption of AI/ML, metabolomics, and blockchain for traceability, safety, and efficacy monitoring.

Global Convergence Platforms

- Development of an international herbal pharmacopoeia and harmonized monograph repository.

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AI Tool Declaration

The authors declare that no AI and related tools are used to write the scientific content of this manuscript.

Conflict of Interests

The authors declare no conflict of interest

Data Availability

Data will be available on request

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